

**Notice of Allowability**

Application No.

10/627,311

Examiner

Suzanne M. Mayer, Ph.D.

Applicant(s)

BROOKS, CYDNEY C.

Art Unit

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to a phone call made to Debra Milasincic (see attached interview summary).
2. ☒ The allowed claim(s) is/are 73-82, 87 and 103-105.
3. ☒ The drawings filed on 7-25-2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Suzanne M. Mayer  
21 July 2005

5.00

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Debra Milasincic and Jill Mellow on 20 July, 2005.

The application has been amended as follows:

**Cancel claims:** 1-72, 83-86 and 88-102.

**Rewrite claim 73 as follows:** A method for identifying an insulin response modulator, comprising contacting a composition comprising insulin-responsive aminopeptidase (IRAP) and human transcytosis-associated protein (TAP) with a test compound and determining the ability of the test compound to modulate binding of IRAP to the human TAP, such that an insulin response modulator is identified.

**Rewrite claim 74 as follows:** A method for identifying an insulin response modulator, comprising contacting a donor vesicle fraction comprising glucose transporter 4 (GLUT4) vesicles with a test compound and determining the ability of the test compound to modulate GLUT4 vesicle translocation, such that an insulin response modulator is identified, wherein said donor vesicle fraction is associated with human TAP prior to contacting with said test compound.

**Rewrite claim 76 as follows:** The method of claim 75, wherein determining the ability of the test compound to modulate GLUT4 vesicle translocation comprises detecting a change in GLUT4 levels in said acceptor vesicle fraction.

**Rewrite claim 77 as follows:** The method of claim 76, wherein detecting a change in GLUT4 levels in said acceptor vesicle fraction comprises detecting GLUT4 levels in said acceptor vesicle fraction after contacting said donor vesicle fraction with the test compound as compared to a control acceptor vesicle fraction.

Art Unit: 1653

**Rewrite claim 78 as follows:** The method of claim 75, wherein determining the ability of the test compound to modulate GLUT4 vesicle translocation comprises detecting a change in IRAP levels in said acceptor vesicle fraction.

**Rewrite claim 79 as follows:** The method of claim 78, wherein detecting a change in IRAP levels in said acceptor vesicle fraction comprises detecting IRAP levels in said acceptor vesicle fraction after contacting said donor vesicle fraction with the test compound as compared to a control acceptor vesicle fraction.

**Rewrite claim 80 as follows:** The method of any one of claims 74-79, wherein said donor vesicle fraction is a GLUT4 vesicle preparation or a low density microsomal fraction.

**Rewrite claim 81 as follows:** The method of any one of claims 75-79, wherein said acceptor vesicle fraction is a plasma membrane fraction.

**Rewrite claim 82 as follows:** The method of any one of claims 75-79, wherein said acceptor vesicle fraction is a plasma membrane fraction and said donor vesicle fraction is a GLUT4 vesicle preparation or a low density microsomal fraction.

**Rewrite claim 87 as follows:** The method of any one of claims 75-79, wherein determining the ability of the test compound to modulate GLUT4 vesicle translocation comprises detecting fluorescence resonance energy transfer from a component of the donor vesicle fraction to a component of the acceptor vesicle fraction.

**Rewrite claim 103 as follows:** The method of claim any of claims 73-74, wherein the modulator identified is a positive modulator.

**Rewrite claim 104 as follows:** A method for identifying an IRAP:human TAP modulator, comprising contacting a composition comprising IRAP and human TAP with a test compound and determining the ability of the test compound to enhance binding of the IRAP to the human TAP, such that the modulator is identified.

**Rewrite claim 105 as follows:** A method for identifying an IRAP:human TAP modulator, comprising contacting a composition comprising IRAP and human TAP with a test compound and determining the ability of the test compound to inhibit binding of the IRAP to the human TAP, such that the modulator is identified.

Art Unit: 1653

2. The following is an examiner's statement of reasons for allowance: Claims 73-82, 87 and 103-105 are drawn to a method which uses the human protein transcytosis-associated protein (TAP; also known as p115 in the prior art) in conjunction with insulin-responsive aminopeptidase (IRAP) and glucose transporter 4 (GLUT4) in order to identify insulin response modulators in a novel function for human TAP. All prior art fails to show or suggest any indication that this specific protein has any role involving insulin response, and thus this is a new and non-obvious function for this protein. Thus, the method utilizing this protein (namely human TAP) which identifies insulin modulators makes the present methods and claims allowable of the prior art.

Claims 73-82, 87 and 103-105 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 or 571-273-8300.

Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Smm*  
SMM  
21 July 2005

*M. Monshipouri*  
MARYAM MONSHIPOURI, PH.D.  
PRIMARY EXAMINER